



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-3405]

Patient Engagement Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a forthcoming public advisory committee meeting of the Patient Engagement Advisory Committee (the Committee).

The general function of the Committee is to provide advice to the Commissioner, or designee, on complex issues relating to medical devices, the regulation of devices, and their use by patients.

The meeting will be open to the public.

DATES: The meeting will be held on November 15, 2018, from 8 a.m. to 5 p.m.

ADDRESSES: Hilton Washington DC North/Gaithersburg, Grand Ballroom, 620 Perry Pkwy., Gaithersburg, MD 20877. The hotel's telephone number is 301-977-8900; additional information available online at: <https://www3.hilton.com/en/hotels/maryland/hilton-washington-dc-north-gaithersburg-GAIGHHF/index.html>. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at:

<https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

FOR FURTHER INFORMATION CONTACT: Letise Williams, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5441, Silver Spring, MD 20993-0002, letise.williams@fda.hhs.gov, 301-796-8398, or FDA

Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the *Federal Register* about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's website at <https://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION: *Agenda:* On November 15, 2018, the Committee will discuss and make recommendations on the topic "Connected and Empowered Patients: e-Platforms Potentially Expanding the Definition of Scientific Evidence." The recommendations will address how FDA can leverage patient-driven platforms, such as social media and registries, to better engage patients and consumers as empowered partners in the work of protecting public health and promoting responsible innovation. Social media and other web platform enablers are facilitating the growth of virtual patient communities. Increasingly, patients and health care consumers are using these platforms to share their health experiences and seek information from other patients and consumers, rather than their health care providers alone. Novel approaches and methodologies are being used to tap into some of these platforms as potentially rich sources of patient-generated health data, which could be used as relevant and reliable real-world evidence (<https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm513027.pdf>).

This meeting will help advance FDA's objective to assure the needs, experiences, and perspectives of patients are included as part of FDA's deliberations involving the regulation of medical devices and their use by patients. For this meeting, FDA is seeking input from the

Committee and the public on whether and how FDA can harness the emerging potential of these patient platforms to better engage patients and consumers as empowered partners in the work of protecting public health and promoting responsible innovation. In addition, FDA is seeking recommendations from the Committee on ways to leverage these platforms to disseminate as well as potentially collect and evaluate health information to and from patients and consumers.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material is available at <https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee-meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the Committee. Oral presentations from the public will be scheduled between approximately 11:15 a.m. to 12:15 p.m. on November 15, 2018. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before October 15, 2018. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by October 17, 2018. Individuals

who do not wish to speak at the open public hearing session but would like their comments to be heard by the Committee may send written submissions to the contact person on or before October 23, 2018.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact AnnMarie Williams at Annmarie.Williams@fda.hhs.gov, or 301-796-5966 at least 7 days in advance of the meeting.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings. Please be advised that, for the round table portion of the meeting, FDA will prepare a summary of the discussion in lieu of detailed transcripts.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: September 18, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-20640 Filed: 9/21/2018 8:45 am; Publication Date: 9/24/2018]